UNITED STATES DISTRICT COURT	
FOR THE SOUTHERN DISTRICT OF NEW YORK	ζ
	v
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The Leonard and Madlyn Abramson Family Cancer:	
Research Institute at the Abramson Cancer Center	•
of the University of Pennsylvania,	: 11 Civ. 09108 (NRB)
	• •
Plaintiff,	ECF Case
	•
V.	Oral Argument Requested
v.	. Oran Angument Requesteu
Craig Thompson M.D. Aging Dharmanauticals	
Craig Thompson, M.D., Agios Pharmaceuticals,	•
Inc., and Celgene Corporation,	•
	· ·
Defendants.	• •
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DEFENDANT AGIOS PHARMACEUTICALS, INC.'S REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS COUNTS I AND III OF THE THIRD AMENDED COMPLAINT

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INTRODUCTION

The Opposition Brief and related submissions filed by the Plaintiff The Leonard and Madlyn Abramson Family Cancer Research Institute at the Abramson Cancer Center of the University of Pennsylvania ("Plaintiff" or "Institute") only confirm that the Third Amended Complaint ("Complaint") fails to state a claim against Defendant Agios Pharmaceuticals Inc. ("Agios"). This is evident on two levels. First, as a matter of pleading, the Institute simply fails to plead facts necessary to the causes of action it pursues against Agios. Those gaps are set forth in Agios' opening brief and below.

But on a more fundamental level, the central premise of the Institute's claim is a legal nullity. Pressed to set out its claim against Agios – a party with which the Plaintiff concedes it has never had any interactions of any kind – the Institute points to no misrepresentation it received, nor any harm it suffered. Rather, the Institute contends that "[t]he fraud... was the misrepresentation to Celgene that Agios could lawfully grant an exclusive license" to certain drugs without the approval of "the Institute and the University." (Pl.'s Mem. of Law in Opp. to Mots. Filed by All Defs. ("Opp. Br.") at 31-32 (emphasis added)) This reflects one of the basic flaws in the Institute's claim. If a misrepresentation were made to Celgene (and none is described in any terms, let alone terms that fulfill Rule 9(b)'s requirement) it is a matter for Celgene, not the Institute. Moreover, if, as the Institute contends, Agios had no right to license intellectual property that it has purported to license to Celgene, the Institute has suffered no harm. Agios cannot license that which it does not own. Beyond these elemental problems, the Institute has no standing, right, or interest to pursue theoretical claims of Celgene. Finally, while the Institute contends that the Agios-Celgene license somehow requires the approval of the University of Pennsylvania ("Penn") as well, Penn in its related complaint makes no such

claim. This underscores both the implausibility of the Institute's claim, and the need to have Penn join this action were the Court to entertain a declaratory judgment claim based on the Institute's convoluted theories.

But here no declaratory judgment action is needed. The focus of the Institute's claims are in two fields of cancer research – autophagy and Phenformin. In both instances, Penn (and for that matter, the Institute) has made no claim that Craig Thompson failed to timely disclose intellectual property in those fields to the extent required under Penn's Patent and Tangible Research Property Policies and Procedures ("Penn Patent Policy"). Further, the Institute concedes that Penn has sought patent protection for the inventive work that Dr. Thompson did in those fields while he was affiliated with Penn. (Compl. ¶ 25) No allegation is made that Agios is even working in those fields, let alone making, using or selling any article or substance that would infringe on any intellectual property rights assigned to Penn by Dr. Thompson. But if it were, the remedy would be simple. Penn could seek to enforce whatever patents it has or will procure from that work. Adding a declaratory judgment to this case adds nothing.

The Institute's invective cannot hide the fact that the claim here is meritless. The Institute had no dealings with Agios and has no basis to prosecute a fraud theory premised on a misrepresentation to an unaffiliated third-party. The only plausible conclusion one can reach from the inflammatory rhetoric of the pleadings is that the Institute's well-financed founders have embarked on a personal attack directed towards a world-renowned cancer researcher who chose to affiliate with a research institute other than the Plaintiff. That is not the basis of viable litigation, and it should be stopped. The Institute's claim that it needs "full discovery" should be accorded no weight. Absent a well pled, plausible, and legally sufficient claim, the Plaintiff has no legitimate basis to gear up the machinery of discovery, which will only waste more money,

impose greater burden, and increase the harassment that animates this litigation. Rather, the case should be dismissed now because it fails to state a claim.

ARGUMENT

I. The Declaratory Judgment Claim Should Be Dismissed

A. The Plaintiff's Brief Fails to Address Penn's Status as an Interested But Absent Party

The Opposition Brief fails to address Penn's status as an interested party whose absence from this litigation would render any declaratory relief unavailing. (*Compare* Opp. Br. at 28-29 with Mem. of Law in Support of Def. Agios' Mot. to Dismiss Counts I and III of the Third Am. Compl. ("Agios Br.") at 9-14) Instead, the Institute contends that Penn's presence is not "essential" and notes that Penn's separate action has been designated as a "related case" to this action. (Opp. Br. at 11, 29) But that only misses the point. The legal question is not whether Penn's inclusion in the declaratory judgment proceeding is "essential" (though it is). Rather, it is whether Penn is an entity with an interest in the outcome of this lawsuit, whose absence would render any declaratory judgment futile (which is clearly the case). (Agios Br. at 9-14 (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967) ("[C]ourts may even refuse declaratory relief for the non-joinder of interested parties who are not, technically speaking, indispensable.")))

That "the University has filed a separate action which has been accepted by this Court as a related case to the instant action," (Opp. Br. at 29) only shines a light on the defects in the Institute's declaratory judgment count. Penn obviously has *not* asserted a declaratory judgment count, and does not even mention anywhere in its 28-page complaint the subjects of "autophagy"

or "Phenformin," the fields of research that are the focus of the Institute's Complaint.¹ The fact that Penn's suit has been designated as "related" obviously does not merge the cases, as even consolidated cases retain their separate identities. (Agios Br. at 13-14) The Institute's effort to distinguish *Aetna Casualty & Surety Co. v. Aniero Concrete Co.*, 404 F.3d 566, 569 n.2 (2d Cir. 2005), based on the fact that it arose in the context of evaluating diversity in two consolidated cases (Opp. Br. at 29) is beside the point. That two consolidated cases are separate for purposes of diversity makes them no less separate for purposes of declaratory judgment jurisprudence.

The Institute's failure to address these issues is only compounded by its own statement at page 19 of the Opposition Brief. There the Institute writes:

Thompson kept the Institute completely in the dark as to the Phenformin Project Plan and the Autophagy Program. Those facts alone suffice to establish the need for a declaratory judgment as to the respective rights and obligations of the Institute and Thompson pursuant to the *Institute Agreement*, and all documents incorporated therein including the *University Patent Policy*. That declaration will also directly relate to any interests purportedly transferred by any means to Agios and any entity that has contracted with Agios, including defendant Celgene Corporation.

(Opp. Br. at 19 (emphasis added)) It would be hard to craft a more succinct statement better demonstrating Penn's interest in the proposed declaratory judgment action. Only Penn and the Institute (and not Agios or Celgene) are parties to the Institute Agreement. Only Penn and Thompson are parties to the Penn Patent Policy (and not Agios or Celgene). Yet the Institute asserts that it is "pursuant" to those agreements that the interests of Agios will be determined. This disconnect, with a party to the key contracts absent from the suit, while parties to the suit are absent from the contracts, eviscerates the viability of the declaratory judgment count. This untenable framework is rendered even more peculiar given the Institute's observation that Penn

In fact, the Penn Complaint focuses on discoveries that were not even in existence during the period complained about by the Institute. (*Compare* Opp. Br. at 16, 30-31 and Burger Aff. Ex. 7 (focusing on Agios' autophagy and Phenformin work in 2008) with Penn Complaint at ¶¶ 29-40, 52-58 (focusing on scholarly publications in late 2009 and 2010 pertaining to IDH1 and IDH2 mutations and 2-Hydroxyglutarate ("2HG") and associated patent applications filed by Agios on that subject in 2010))

negotiated with Agios about "autophagy" and "Phenformin" at the same time Penn knew that Dr. Thompson was affiliated with Agios. (Opp. Br. at 18, 31) Whether or not the Institute "was in the dark" (*id.* at 19), Penn – which was charged with negotiating licenses for intellectual property developed by Penn faculty under the Penn Patent Policy that the Institute says is essential to its claim – clearly was not.² How these various issues might be resolved, if they even needed to be resolved, would unquestionably require the presence of Penn. Penn was a party to the key contracts, assignee on the key patent applications, negotiator of the relevant licenses, and owner of the relevant intellectual property. But for whatever reason, the Institute has not joined Penn, an interested party on multiple levels, to its declaratory judgment claim. Without Penn Count I should be dismissed.

B. The Plaintiff's Brief Underscores That This is an Inventorship Dispute

The Institute attacks, but does not actually address, Agios' observation that the declaratory judgment count must be dismissed because an inventorship dispute over a pending patent application is reserved exclusively for the U.S. Patent and Trademark Office. (Agios Br. at 15-18) Labeling the point "fraudulent[]," the Institute dismisses Agios' argument as irrelevant. (Opp. Br. at 29) The Institute's only support for its overheated rhetoric is the observation that the Institute Agreement covers "[a]ll Intellectual Property, whether or not patentable or copyrightable" (*Id.*) But that observation about the Institute Agreement does not address how this particular dispute involves intellectual property other than patents. It is obvious that this case has nothing to do with copyright law, and as the Institute itself concedes, it is not a trade secret case. (Opp. Br. at 30 ("Agios acknowledges that the Institute is not making any

The Institute's claim that it was "in the dark" at the same time Penn was negotiating with Agios with full knowledge of Dr. Thompson's affiliation, is also extremely disingenuous. In another context, the Institute has emphasized the close and overlapping structures of Penn and the Institute. (*See* Opp. Br. at 11 (noting that the University appoints five of the eleven Institute directors and that the "President of the University and the Dean of the University Medical School are currently members of the Institute's Board of Directors")) While Agios had no disclosure obligations to the Institute in any event, the notion that the Institute was "in the dark" on a matter where Penn was fully engaged is highly implausible.

trade secret claim ")) Furthermore, the Institute's continued focus on autophagy and Phenformin, and Penn's patent applications relating to these subjects, further bolsters the patent aspect of this case. (Id. ("Thompson's work at the Institute included a patent application relating to Autophagy and research relating to Phenformin.")) Autophagy and Phenformin are broad subject matters; autophagy refers to a process in cell biology and Phenformin is an anti-diabetic drug invented over 40 years ago. See, e.g., http://www.nature.com/nature/journal/v469/n7330/ full/nature09782.html; http://www.diabetesnet.com/about-diabetes/diabetes-medications/ metformin. The Institute no more owns these subjects than it owns photosynthesis or penicillin. Penn has filed patent applications based on work that Dr. Thompson did pertaining to autophagy and Phenformin. (Mem. of Law of Def. Craig Thompson, M.D. in Support of Mot. to Dismiss the Third Am. Compl. ("Thompson Dismissal Br.") at 9-10; Arfa Decl. Exs. 4-8) Dr. Thompson is listed as an inventor on each of these patent applications, indicating that he complied with the Penn Patent Policy and did his part in disclosing and assigning any intellectual property pertaining to these subject matters to Penn. If the Institute contends otherwise, then its position implicates the inventorship on these patents, and if not, the Institute then concedes that Dr. Thompson fulfilled his duties. Either way it is now up to the PTO to determine whether this intellectual property deserves patent protection. If patents issue, Penn as the patent-holder may enforce its rights under such patents by bringing an infringement suit. If the Institute has any right to share in such proceeds with Penn under the Institute Agreement it may do so as a matter of contract law. If no patents issue then the matter is in the public domain. A declaratory judgment claim is not necessary.

The Institute's repeated focus on the fact that Agios negotiated with Penn for licenses pertaining to autophagy and Phenformin, that it did not take any licenses, and that it prepared a

document dated 2008 "which listed only five programs to be explored, two of which were the 'Phenformin Project Plan' and the 'Autophagy Program'" (Opp. Br. at 31) is of no relevance. The fact that Agios explored programs relating to autophagy or Phenformin, or that Agios had unsuccessful licensing discussions with Penn, is not actionable. Parties negotiate, but do not reach agreement, all the time. And even if Penn were to hold patents in these fields, Agios would have to make, use, offer to sell, or sell the inventions claimed by those patents to be liable. 35 U.S.C. § 271. Were that the case (something not alleged), Agios would be liable to *Penn* as the patent holder, not to the Institute. Indeed, whatever rights were created by Thompson with respect to autophagy and Phenformin, it is Penn, and not the Plaintiff, that holds these rights. (Thompson Dismissal Br. at 9-10; Arfa Decl. Exs. 4-8) Notably, in its own lawsuit, Penn asserts no claims whatsoever pertaining to autophagy or Phenformin, and, instead focuses on an entirely different subject – IDH. (*See* Agios Br. at 22)

II. The Fraudulent Misrepresentation Claim Should Be Dismissed

The Institute's attempt to explain its fraudulent misrepresentation claim against Agios only highlights how untethered the allegations are from basic principles of law and logic. The Institute articulates its central claim against Agios as follows:

The fraud by Thompson through Agios, of which he was a principal, was the misrepresentation to Celgene that Agios could lawfully grant an exclusive license with respect to any drugs resulting from the Agios cancer metabolism research platform without the knowledge, approval and participation of the Institute and the University as to matters that were the subject of Thompson's research funded by the Institute for over twelve years.

(Opp. Br. at 31-32) While this sentence presents syntax challenges and is vague in the extreme, no matter how one reads it, it cannot support a claim for fraud by the Institute against Agios.

Rather, it underscores the Complaint's failure to state a plausible claim for fraudulent misrepresentation with the specificity required under Rule 9(b), in at least four ways.

First, however interpreted, this sentence – as well as the rest of the Opposition Brief and the Complaint – fails to explain who made what misrepresentation, and when and where it was made. If read to refer to a fraud by Thompson (which is a fair reading, given that the sentence starts with the phrase "The fraud by Thompson"), the Institute fails to address the basic question of what the factual basis is for a claim of fraud by Agios. If read to suggest that Agios is liable under some form of agency theory, that assertion is unsupported and still fails to explain the circumstances of an alleged misrepresentation by Thompson directed to Celgene in connection with the Agios-Celgene transaction. (See Opp. Br. at 31-32) Nothing is offered – either in the Complaint or the Opposition Brief – to explain what role, if any, Dr. Thompson had in the negotiation of that transaction. Nor is there even an allegation that Dr. Thompson was an officer, director, or employee of Agios during the period in which the Celgene transaction was negotiated.

Nor does the Institute explain how a claim of fraud against an individual affiliated with a corporate entity survives the carefully-crafted representations and warranties that companies make in complex agreements such as a multi-hundred million dollar pharmaceutical licensing agreement. Such agreements are invariably integrated and contain provisions defining which individuals' knowledge might be imputed to the corporation. It also fails to address whether the hypothetical representations were sufficiently unrelated to the subject matter of the agreement so as not to be precluded under New York's doctrine that contract claims cannot be transformed into fraud claims. *See, e.g., Gould Paper Corp. v. Madisen Corp.*, 614 F. Supp. 2d 485, 492 (S.D.N.Y. 2009). In short, despite its wishful assurance that Rule 9(b)'s standards "have been amply satisfied" (Opp. Br. at 25), the Opposition Brief offers no more detail on these matters than the Complaint, which offers no information at all. (*See* Agios Br. at 18-24)

Second, putting all of this aside, the Opposition Brief confirms that the alleged "misrepresentation" was "to Celgene." (Opp. Br. at 31 (emphasis added)) But the Institute, which confirms that it had no interaction whatsoever with Agios (id. ("Agios thus concedes that it had no dealings whatsover with the Institute" (internal quotations omitted))), cannot claim fraud based on an alleged misrepresentation to an unaffiliated third party. (See Agios Br. at 20-21)

Third, the sentence quoted above implies that Agios is categorically banned from entering into any agreement "without the knowledge, approval and participation of the Institute and the University as to matters that were the subject of Thompson's research funded by the Institute for over twelve years." (Opp. Br. at 32) But the notion that Agios cannot operate in any field in common with Dr. Thompson's funded research, absent Institute approval, is preposterous. No legal doctrine supports such a notion, which would raise a host of problems, including significant anti-competition constraints on parties who never agreed to such provisions. Nothing in the Penn Patent Policy suggests such an outcome, and nothing in the related Penn Complaint suggests any affinity by Penn for such overreaching. Even non-compete agreements cannot be read in such a manner. See, e.g., EarthWeb, Inc. v. Schlack, 71 F. Supp. 2d 299, 312 (S.D.N.Y. 1999) (reciting limitations on non-compete covenants under New York law).

Finally, if the Institute's fraudulent misrepresentation claim is that Dr. Thompson, through Agios, misrepresented that Agios could grant a license to Celgene for intellectual property that was owned by Penn and/or the Institute, then by definition, neither Penn nor the Institute would suffer any harm. The premise of the Institute's chain of reasoning is that Agios and Thompson cannot confer any such rights upon a third party, and it is axiomatic that a party cannot transfer rights that it does not possess. *See, e.g., Mediatek, Inc. v. Sanyo Elec. Co.*, 2007

WL 5186792, at *5 (E.D. Tex. Apr. 16, 2007) ("[T]he patent rights transferred-and not label the parties gave the transfers-determines what rights [the purported assignee] obtained in the patents-at-issue."). That being so, the Institute obviously has lost nothing, and suffered no damages.

In sum, no interpretation of the Institute's fraud theory adds up to a cognizable fraudulent misrepresentation claim, let alone a claim pled with the heightened specificity required under Rule 9(b).

CONCLUSION

For the reasons set forth above and in Agios' opening brief, as well as in Dr. Thompson's opening and reply briefs in support of his motion to dismiss, Agios respectfully requests that the Court dismiss, with prejudice, Counts I and III of the Complaint.

Dated: April 27, 2012

Respectfully submitted,

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